

Usermanual

1.1 Release



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1 INTRODUCTION

1.1 Intended Use

Hemolyzer 3 hematology analyzer is a fully automated cell counter designed for *in vitro* diagnostic use. The instrument was developed for small clinics or laboratories.

1.2 The Instrument

Hemolyzer 3 is a fully automated, bench top hematology cell counter.

It implements the so-called Coulter-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells.

The analyzer features a color graphical LCD display module and a foil keypad of 29 keys including 6 software buttons (with icons), 6 function keys (above LCD) and has a START button.

The instrument allows printing reports to an external printer (USB port), or can have an optional built-in printer module.

Its internal memory is capable of storing 1000 records with full histograms, and individual patient data. QC measurements are stored in a separate database. Upgrade of the software operating the instrument is possible USB flash memory device. The instrument allows connecting to a host computer for uploading records stored in its memory through a USB SLAVE port (USB B) or serial link (RS232). Archiving and restoring of records to and from USB flash memory device is also possible.

NOTE: If the equipment is used in a manner different from which the manufacturer specified, the protection provided by the equipment may be impaired. Misuse of equipment or use other than its intended purpose will invalidate conditions of warranty. The accuracy and precision may also be impaired.

1.3 Patient Testing

The analyzer can process 60 samples per hour. Samples can have individual sample data, and additional parameters. You can print results to an external or to the optional built in printer. The user can customize the report format.

Hemolyzer 3 determines 20 hematology parameters including three-part WBC differential. The instrument requires 25µl of whole blood sample:

WBC	total white blood cell count
LYM	lymphocytes count
MON	monocytes count
NEU	neutrophil granulocyte count
LYM%	lymphocytes percentage
MON%	monocytes percentage
NEU%	neutrophil granulocyte percentage
HGB	hemoglobin
RBC	red blood cell count
HCT	hematocrit
MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
RDWcv	red cell distribution width
RDWsd	red cell standard deviation
PLT	platelet count
PCT	platelet percentage
MPV	mean platelet volume
PDWcv	platelet distribution width
PDWsd	platelet standard deviation

1.4 Reagents

Accuracy is guaranteed only if reagents supplied by the manufacturer are used

Hemolyzer Dil-DIFF (diluent):	Isotonic saline solution, used to dilute whole blood samples and to rinse the fluidic system between measuring procedures.
Hemolyzer Lyse-DIFF (lyse):	Creates hemolysate for 3-part WBC differential and for total WBC and HGB.
Hemolyzer Cleaner (cleaner):	For cleaning process of the fluidics.

1.5 Technical Operation

As Hemolyzer 3 is a fully automated instrument, operating it requires minimal training or technical support. Operator interaction is reduced to the following:

- Perform a *Blank Measurement* in case the instrument is not used for a specific time
- Enter sample and/or patient data
- Apply the sample for analysis
- Print results either one-by-one, or in groups by selecting records from the database
- Perform simple weekly maintenance, as described later in this description (8.2).

1.6 Calibration and Quality Control

Hemolyzer 3 arrives to your laboratory factory-calibrated and ready to use. However, calibration needs updating whenever you find that the results have slightly changed, or a different or new control material is used. With each control material you receive for the instrument, you will find a control sheet listing the parameters the instrument should match. Perform these calibrations as explained in a later chapter (8.3).

Use Quality Control procedures to check for proper calibration and performance of the analyzer. Running these samples should happen on a regular basis, as also explained in a later chapter (8.4).

1.7 Instrument features

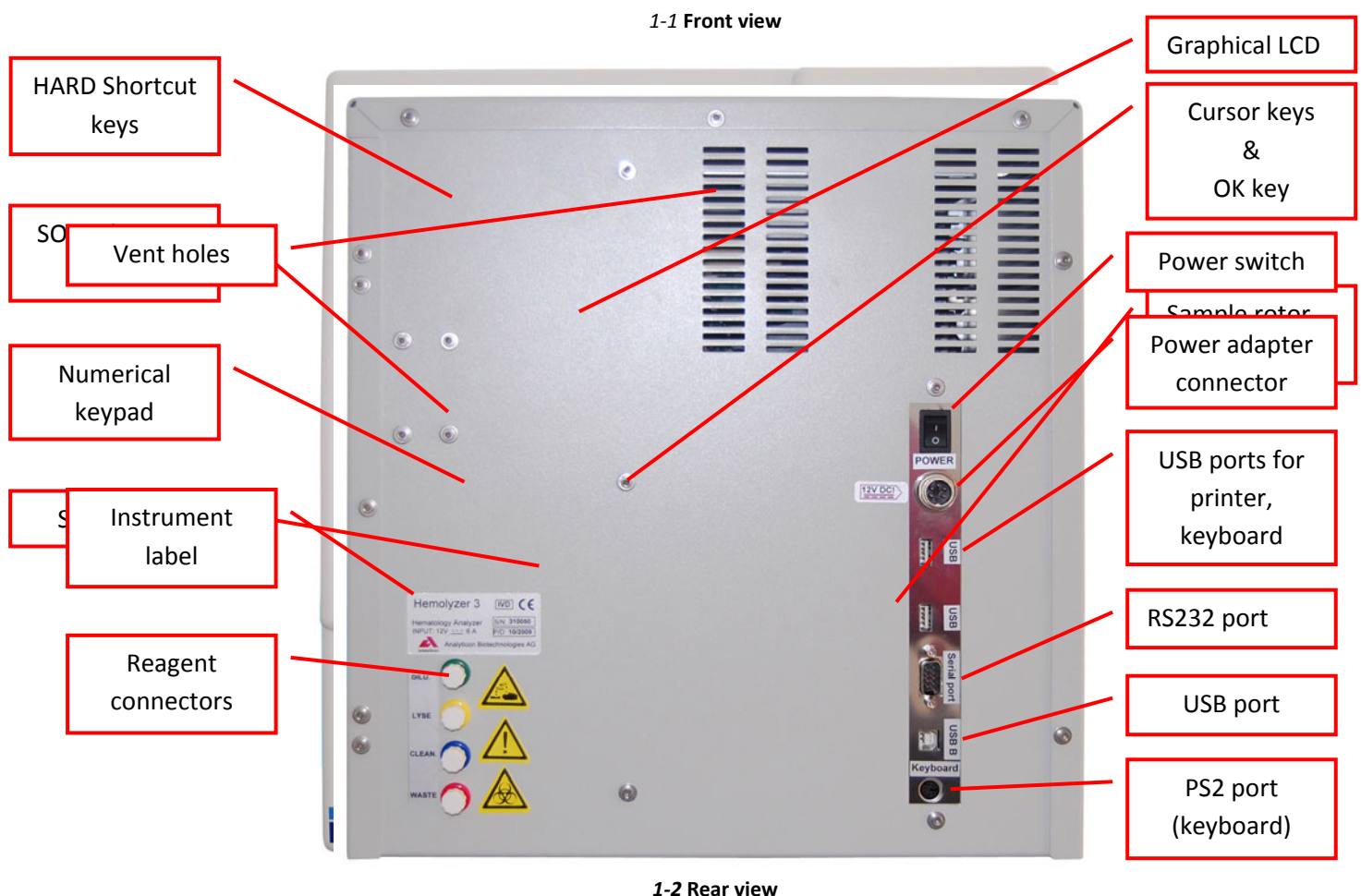
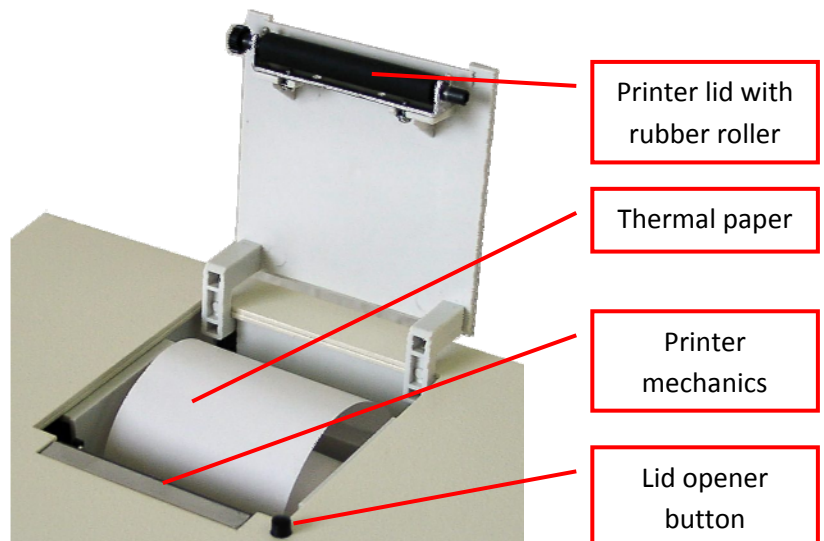


Figure 1-3 shows the open built-in printer using roll paper inside.

Press the protruding button to open the lid. Let the thermal printer paper fall into the housing with its open end toward the paper tearing (towards the front of the instrument). Hold the open end of the paper and close the lid so that the end of the paper gets clipped between the black paper guide and the printer mechanics.

You can select to use this printer in the **"Printer Settings"** menu (see chapter 8.6.2).



1-3 Built-in printer

The analyzer works with an external power supply. Figure 1-4 shows the power supply unit generating 12VDC. The power supply module has a so-called auto range input, allowing operation on 230V or 115V power system. The power supply complies CE and UL safety certifications.



The input socket is a standard power cable connection shipped with the analyzer, the output is a special, lockable socket as shown in the picture.

Only the provided power supply shall be used with the instrument. ("Protek Electronics Corp." Model ID: PUP80-12-N8)

1-4 Power supply

1.8 Parts of the Analyzer

Hemolyzer 3 hematology analyzer is composed of three main units:

Fluidic System:	Performs sampling, diluting, mixing, and lysing functions. Generates the regulated vacuum used for moving cells through the aperture during the counting process.
Data Processing System:	Counts, measures and calculates blood parameters, generates and stores numerical results and histograms.
Control Panel:	Features an LCD display, a 29-button keypad, and USB ports and serial (computer) interfaces.

1.9 Function of the Fluidics

For the Schematics of the fluidics system, see Section 9.

Sample aspiration and dilution:

Stages of the blood testing process	
a.	25 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated through the sampling needle and mixed with 4 ml of diluent and stored in the mix chamber (mix dilution).
b.	35 µl of primary dilution is aspirated and then added with 4 ml of diluent into the RBC chamber (RBC dilution)
c.	The primary dilution remaining in the mixing chamber flows via the tubing into the WBC chamber where the necessary (preset) amount of lysing reagent is added (WBC dilution).

Table 1.

Dilution rates used within Hemolyzer 3:

- Primary dilution 1:160
- RBC dilution 1:18 000
- WBC dilution 1:192 (dependent on lyse amount, default volume is 0.8 ml)

Measurement times:

- WBC count 2-6 seconds (depends on the total WBC count)
- HGB measurement 2 seconds
- RBC/PLT count 5 seconds

1.10 Control Panels

START button - Pressing and releasing the START button triggers an analysis cycle.

Status indicator - A two-color (red/blue) LED is located near the START button.

Its actual color indicates the status of the analyzer.

LED color	Analyzer status
● Green	The analyzer is ready to work. Analysis can be initiated.
* Red blinking	Blood sample can be removed when the LED blinks red 3 times and the instrument beeps 3 times.
● Red	The analyzer is currently performing an analysis. No new measurement can be started.
● Orange	The analyzer is performing a maintenance process.
* Orange blinking	The instrument is in stand-by and display light is off.

1.11 Display

The display is 320 x 240 dots, high contrast backlit color graphic LCD module.














1.12 Keyboard

The foil keypad is composed of the following (shown in Section 1.3 - Figure 1):







- **Numeric keys** for entering numerical data, and selecting menu items
- **Function keys** with specific functions. These functions are menu-dependent and are indicated by icons appearing above the keys
- **Hardware function keys (short-cut keys)** for easier navigation between menus
- **Cursor control keys** ↑ and ↓ for moving between database items, ← and →, for moving between parameter columns or menu levels
- **START key** for initiating an analysis cycle
- **OK key** for confirming data
- **Del key** for deleting characters
- **Help key** for HELP function

Function keys

Below is a list of icons and functions assigned to the soft-keys (function keys)

Function key	Action triggered
	Exit from actual menu or action
	Leave data-entry menu without saving changes (Cancel)
	Confirm the results or changes made (OK)
	Repeat action (e.g. Blank measurement)
	Display histograms of the highlighted patient ID or QC Lot No.
	Enter/modify sample/patient data, patient type selection
	PAGE-UP / PAGE-DOWN key in a multi-page menu
	Change scaling of Levey-Jennings chart (16 or 64 entries)
	Confirm error
	Go to local menu (database, measurement)
	Limits
	Stop a running process
	Show data in table format

Below we list the icons and functions assigned to so-called hardware function buttons

Function key	Action triggered
	Information
	Measuring process at once
	Database
	Utilities menu
	Printing function
	Exit menu

1.13 Control Material

Hemolyzer 3 allows continuous monitoring with HemolyzerCont3 control (control blood). Specification for this material (assay values and allowed tolerances along with expiry date) is always enclosed with the approved control material.

1.14 Accessories

Below is a list of accessories shipped with your Hemolyzer 3

Hemolyzer 3 Hematology Analyzer

Hemolyzer 3 User's Manual (this booklet)

Hemolyzer 3 Reagent Tubes (with colored connector caps)

Diluent tube (green)

Lyse tube (yellow)

Clean tube (blue)

Waste tube (red)

Hemolyzer 3 Cleaning Tube Kit.

Hemolyzer 3 Caps for reagent containers (matching connector colors).

Hemolyzer 3 Waste Container (20 L).

Hemolyzer 3 External power supply and power cable.

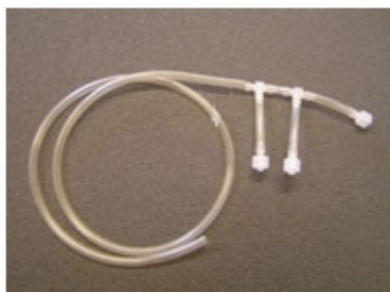
Hemolyzer 3 Spare part: pump tube.

Hemolyzer 3 Tube adapters.

Hemolyzer 3 Thermal roll-paper.



1-5 Reagent tubing



1-6 Cleaning tube kit

1.15 Specifications

Sample volume	25 µl of whole blood, 50 µl of whole blood in pre-diluted mode
Chambers	3 chambers for diluting whole blood and counting; 1:MIX, 1:RBC, 1:WBC
Reagent system	Isotonic Diluent, Lyse, Cleaner
Aperture diameter	80 µm (RBC/PLT), 100 µm (WBC)
Throughput	60 tests/hour

Characteristics	Accuracy	Reproducibility error (CV)	Carry-over sample to sample	Test range	Unit
WBC	3%	<3%	<1%	4.0-20.0	10 ³ /µl
RBC	3%	<3%	<1%	4.0-15.0	10 ⁶ /µl
HCT	3%	<3%	<1%	25.0-50.0	%
MCV	2%	<1%	N/A	5-90	fl
HGB	2%	<2%	<1%	9-16	g/dl
PLT	5%	<4%	<3%	200-900	10 ³ /µl

Sampling method	Open tube system with automatic sample rotor.
Sample types	Human(general), male, female, baby, toddler and child (built-in reference ranges)
Clog prevention	High-voltage pulse on aperture in each analysis cycle; chemical cleaning; high-pressure backflush of aperture with Cleaner reagent.
Cleaning procedure	High-voltage burst of the aperture, high-pressure back-flush, chemical cleaning of the aperture using Cleaner reagent.
Quality control	6 QC levels, QC parameters include: mean, ± range, SD and CV for all measured and calculated parameters, 16- and 64-day Levey-Jennings charts, separate QC database.
Calibration	1 or 3-measurement automatic and manual (factors) calibration of WBC, HGB, RBC, PLT, MCV, RDW and MPV absolute. Independent calibration of pre-diluted mode.
Multi-user feature (advanced feature)	3-level multi-user operation with selective privilege levels, user identification with ID and password.
User interface	Easy-to-use, menu driven user interface with 6 software buttons (with graphic icons), 6 hardware function buttons, cursor and numeric keys.
Languages available	English.
Data capacity	1000 results, with RBC, PLT, WBC 3-part histogram
Host computer interface	USB B port or RS-232 serial link.
Data back-up method	USB mass storage device; AnalyticonLab data management software.
Software upgrade method	USB A port using USB mass storage device
Printer interface	USB with support for HP printers, color and monochrome printout.
Built-in printer	Seiko LPTH-245 „Easy Paper Operation” thermal printer module, 58 mm wide roll paper, full report with histograms
Display	320x240 -dots, high-contrast, backlit, color graphics LCD
Keypad	29 foil keys + separate START button, red/green/orange machine state light.
External keyboard	Standard PS/2 compatible or USB
Power requirement	12VDC, 6A, 72W max. operating power.
Power supply unit	External, auto-ranging power unit for 100-120 or 200-240 VAC, 50–60Hz.
Operating temperature	59–86 °F (15–30 °C). Optimal temperature is 77 °F (25 °C).
Dimensions (W x D x H)	340 x 414 x 380 mm
Net weight	15 kg.

2 INSTALLATION

2.1 General information

This chapter provides instructions for the installation of the Hemolyzer 3 hematology analyzer. Follow the procedures described below correctly to ensure proper operation and service. Please carefully read and follow all instructions in this *User's Manual* before operating Hemolyzer 3.

The Hemolyzer 3 hematology analyzer is a precision instrument. Handle accordingly. Dropping or other improper handling of the instrument will disturb calibrated mechanic and electronic components and/or cause other damage.

Always handle the instrument with care.

2.2 Environmental factors

Operate Hemolyzer 3 within the ambient temperature range of 15-30°C and relative humidity of 65% \pm 20%. The optimum operating temperature is 25°C.

Avoid using the instrument in areas of extreme high or low temperatures or where it is exposed to direct sunlight. If kept at a temperature lower than 10°C, the instrument should sit for an hour at the correct room temperature before use.

Reagents should be stored at a temperature range of 15-30°C.

Place the instrument in a well-ventilated location. Do not place it near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television receiver, radars, centrifuge, X-ray devices, fans, etc.).

Operation at an altitude over 3000 meters (9000 ft) not recommended.

Instrument is safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.

Environmental and electrical characteristics provide accuracy and precision of the instrument and maintain a high level of operational safety for lab personnel.

2.3 Electrical requirements

Hemolyzer 3 comes with a power cord appropriate for your power system. Proper use of the appropriate power cord assures adequate grounding of the system.

WARNING: Improper grounding of Hemolyzer 3 bypasses important safety features and may result in electrical hazard.

2.4 Space requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Consider the following space requirements:

- Select a location near a power source and close to a suitable drain.
- Place the unit on a clean and level surface.
- Leave at least 0.5 m space on both sides and above the instrument to access pneumatics and (optional) built in printer. Provide a minimum of 0.2 m between the rear panel and the wall to allow for heat dissipation and tube clearance.

- Install the reagents in a suitable place that will make your work easy. The best place is on the ground, below the supporting desk of the instrument. The pneumatics system is capable of aspirating reagents from containers being 1.0 m below the reagent inputs. Make sure the reagent tubes are not bent, broken, twisted or blocked in between the desk the instrument is on and the wall behind. Such circumstances can result in instrument operation failure.
- DO NOT PLACE the reagents above the instrument, as there can be a risk of falling and spilling.

WARNING: Install the unit on a table or workbench. If the unit was installed without a supporting desktop under the unit, there is a possibility that the analyzer could accidentally fall.

2.5 Peripherals

Connect external peripherals only when both the instrument and the peripheral device are off. Possible peripherals are:

- external printer
 - the printer must be recommended by authorized technician
 - the printer must be approved and listed
 - the printer must have a CE mark
- external keyboard
 - the external keyboard must be approved
 - the external keyboard must have a PS2 connector, or suitable USB adapter
- link to host computer via serial or USB port
 - serial link cable must be approved by technician
 - USB B port (linking to host computer) requires a USB A-B cable and USB driver software (contact service)

2.6 Reagents and waste handling

Reagents should be handled according to national or international regulations.

WARNING!

Reagents may cause corrosion and skin irritation. If any of the liquids leaked onto the cover of analyzer or the furniture, wipe it off immediately. In case of skin contact, rinse the liquid off with plenty of water.

Waste generated by the unit is biohazard material. Handling and disposal must happen according to regulations regarding reagent systems.

WARNING!

Waste contains poisonous substances (because of chemical content) and human origin substances meaning biohazard. These substances are representing potential danger to environment. For this reason, safe handling of the waste liquid is very important.

2.7 Maintenance

The user should check the following components weekly:

- bottom of washing head for salt build up – should be wiped off with a damp cloth
- tubing system – by opening the side door and looking for any liquid leakage. If you experience leakage, contact authorized technician.

Caution:

The following parts must NOT be opened or serviced by the user:

- power supply
- instrument housing, and electronic boards

2.7.1 Cleaning

Clean the instrument and its power supply on the outside only, using a damp cloth with a soft detergent. DO NOT let liquids get inside the units.

2.7.2 General points

The manufacturer guarantees work safety reliability and general characteristics under the following conditions only:

- services and repairs are performed by an authorized technician
- the electrical system of the laboratory follows national and/or international regulations
- the system is operated according to instructions contained herein

2.8 Unpacking and installation

Carefully remove Hemolyzer 3 from the shipping carton. Inspect the instrument for any visible signs of damage incurred during shipping. Would you find any damage, file a claim with the carrier or your distributor immediately. Check the accessories received against the packing list. Contact Service if anything is missing.

CAUTION! Prior to initial operation, allow the instrument to reach room temperature (approx. 2 hours). Rapid temperature changes in an operating unit can lead to water condensation, which may damage electronic parts.

Place the instrument on a firm work surface in the designated work area, near an appropriate AC electrical outlet. The connection **MUST** be grounded.

NOTE Before making connections: Make sure that all power is in “OFF” setting before connections (printer, external keyboard) are made. Carefully read all literature accompanying the instrument and its accessories. Pay particular attention to the operating procedures for the external printer.

2.8.1 Keyboard and external printer

Attach the keyboard cable to the round “KEYBOARD” port on the back of the instrument. Attach both ends of the printer cable to the appropriate ports on the printer and Hemolyzer 3. Attach the AC adapter to the printer (if required) and plug it into an AC outlet.

2.8.2 Host Computer

The instrument has a built-in serial port that allows connection to a host computer. Results, including histograms, may be exported. Serial (USB) I/O settings can be found in Settings. For installation instructions, please contact Service.

2.8.3 Power supply

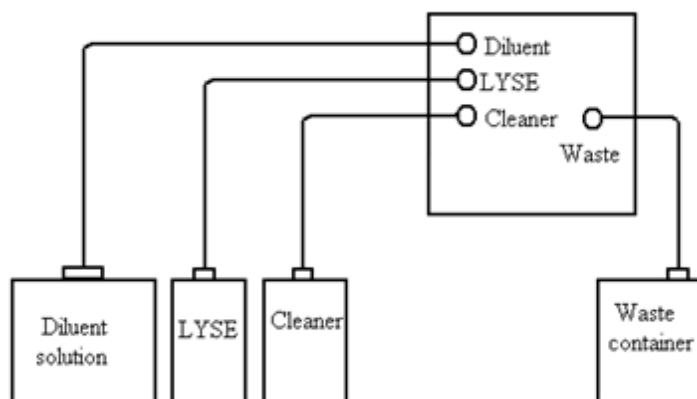
Connect the power supply to the instrument. Attach power cord outlet to the external power supply of Hemolyzer 3 and plug the other end into a properly grounded AC outlet.

Do not switch on the instrument before connecting the external power supply to the instrument and to the AC outlet, as well as before connecting an external printer or a keyboard to the instrument.

2.8.4 Reagent Containers

Place the reagent containers near the instrument, to an accessible location. Do not place the containers to a higher position than that of Hemolyzer 3, because would a tube come off its connector, the fluids spoil out. Use the supplied connecting tubes and special bottle caps. Be sure that the color on each tube, cap and connector in the back of the instrument match. You can for example, place the reagent containers below the desk the analyzer is installed on, as the instrument has sufficient power to draw the liquids from a lower location.

All containers should be left open (do not block the small air vent hole on the special container caps) in order to provide free airflow. (For connections, see below)



2-1 Reagent container connection

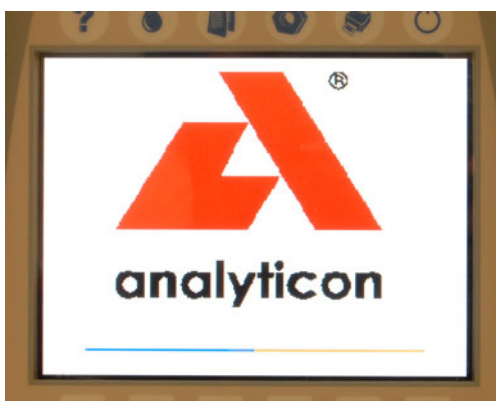


WARNING! *Reagents may cause corrosion and skin irritation. If any of liquids leaked to cover of analyzer or the furniture, it has to be wiped down immediately. In case of skin contact the liquid has to be rinsed by plenty of water.*

2.9 Turning the Instrument ON

In case you use an external printer (for information, read manual shipped with the printer) connect it and turn it on.

Turn Hemolyzer 3 on using the power switch on the rear panel. The On position is marked by the (I) symbol.



During start-up, the following screen is displayed. The software version number appears few seconds later, when the software starts.

Database			
Sample ID	Patient ID	Date	WBC
111		01.03.2008 15:43	17.7
112		01.03.2008 15:49	18.0
113		01.03.2008 15:53	17.7
0		01.03.2008 16:11	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:13	0.00
0		01.03.2008 16:13	0.00
0		01.03.2008 16:13	0.00
0	Blank	25.03.2008 11:18	0.00
0	Blank	25.03.2008 11:55	0.00

When the software version is loaded, the DATABASE is displayed without any pneumatic initialization (default setting). Pneumatic movement is initiated only when necessary for the relating process.

The default setting can be changed at Service Menu level, in this case the instrument will start with pneumatic initialization giving the possibility to

CAUTION! *Wait 5 minutes before initiating any measuring process to allow the instrument to reach the optimal working temperature.*


In some cases, a priming cycle is necessary prior to sample introduction. The instrument will perform the cycle automatically if the fluid sensors are on and additional liquid in the tubing system is required. Run a priming cycle in case of:

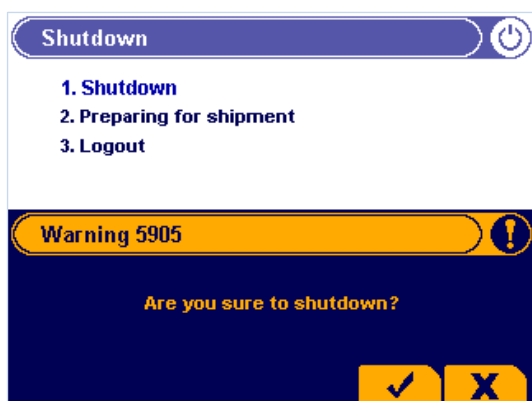
- installation
- extended time out of use
- replacement of any component related to the Fluidic System
- replacement of reagents with instrument turned on


2.10 Turning the Instrument OFF

The instrument should never be switched off by simply flipping the power switch on the rear panel. Doing so may result in erroneous operation during later use. It can be so, because the instrument uses different kinds of solutions, one of which is the so-called diluent. This liquid is an isotonic saline solution containing salt. Would it not be washed out of special units of the instrument, or would chambers not be filled with this solution may lead to dust condensation or salt build up.

Therefore always follow the instructions below when switching the instrument off.

Press EXIT key  on the front panel. The following screen is displayed.



Select Shut down. A message appears: (Warning 5905). When prompted, press  to confirm. Hemolyzer 3 will display a message (Warning 5906) and give a tone indicating that it is safe to shut it off.

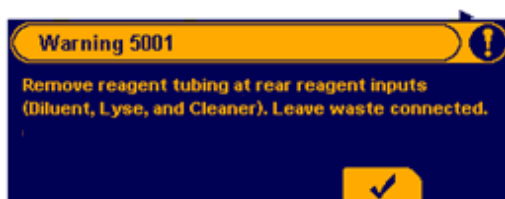
Turn off the instrument using the power switch on the rear panel. The Off position is marked by O symbol.

Item three (3) is only available in multi-user mode.

2.11 Preparing for shipment

The second item in the shut down menu should be used when the instrument is to be shipped or left unused for a longer time (more than 1 week). The instrument will ask you to use the cleaning tube kit and 100ml of distilled water.

Follow the instructions appearing on the display.

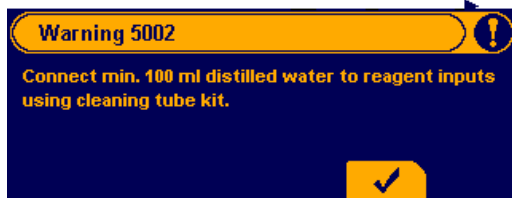


EXIT

Preparing for shipment (2)

The user must remove tubing connectors, so the system could be drained.

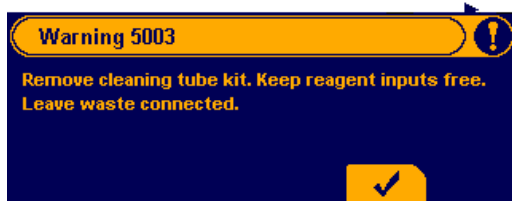
Leave the waste connector attached.



Next, you should connect the cleaning tube kit to the reagent inputs, submerging the free end in a bottle containing at least 100 ml of distilled water.

Cleaning tube kit connected

The analyzer will flush any remaining reagents from the system into the waste container.



As a next step, the analyzer asks you to remove the cleaning tube kit.

When finished, the analyzer prompts you to power off the system. Remove the waste connector after shutting down.

2.12 Emergency handling

In case of emergency situation - like instrument catching on fire (short-circuit, etc.) - cut off power immediately and use a fire-extinguisher if necessary.

3 MENU SYSTEM

3.1 General Information

This chapter contains information about the structure and usage of the software implemented menu structure.

This integrated software controls instrument operations including calculation and evaluation of measured data, displaying results and information screens, storage and recalling of data.

3.2 Navigating in the Menu System

The instrument uses a menu system to initiate actions and to access settings.

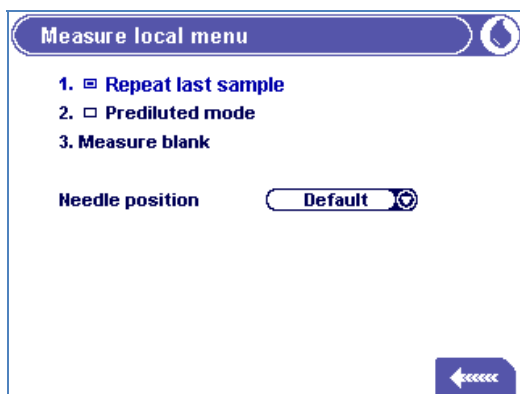
There are four possible ways to navigate between menus and menu items:

There are 6 function keys above the LCD screen. You can use these buttons to navigate between main functions of the instrument.



These keys are short cut keys: by pressing any of them, you can directly access main functions, whichever submenu you are in.

If you use an external keyboard, you can access these functions with keys F8 through F12. (indicated in Menu Structure as well).



By pressing the short-cut keys, you can activate main functions (Information, Measure, Database, Utilities, Printing, Exit) of the instrument. Below the short-cut keys (in the upper part of the screen) you will find tabs showing which main function is active or which are accessible directly.

- a. You can select a menu item (move highlight) with the \uparrow and \downarrow keys and press the **OK** key to enter or activate the highlighted item.

Within a submenu, you can press the  function key to return to the previous menu level.

This method is suggested while learning instrument operation.

- b. Pressing the numeric key corresponding to the menu item allows selection and access of an item without the need to additionally press the **OK** key. This method is more efficient after the user knows the menu structure.

If a menu item opens a submenu, then the item has a ► symbol on the right of the menu line.

Some results are displayed in table format. The following keys may be used to browse the database:

3 ↑ page up

9 ↓ page down

1 ↑ jump to top of list

7 ↓ jump to bottom of list

Several menus have items with boxes in front of the text. These indicate two-state options. The *selected (active)* state is indicated with a filled box, the *deselected (inactive)* state is indicated with an empty box. Pressing **OK** toggles its state.

Other items have circles in front of the text. These are “radio-buttons”, divided into groups separated by horizontal lines.

The function of these groups is that only one item of the group can be selected, and this is indicated with a filled circle in front of the selected item. Selecting an item of the group will move the filled circle in front of this item, emptying the circle of the old selected item.

3.3 Menu structure

The following outlines Hemolyzer 3 menu functions.



Information/Help

Displays help for the current screen



Analysis/Measurement



(Measurement local menu)

- | | | |
|----|-----------------------|---|
| 1. | Repeat last sample | Repeats last sample tested. Previously filled in sample parameters (sample ID, Patient ID, etc.) will be used for the consecutive sample. "Repeat mode" appears in lower left section of the screen |
| 2. | Prediluted mode | Activates automatic calculations for 1:5 externally diluted sample ("1:5" appears in lower left section of the screen). |
| 3. | Measure Blank | Performs a Blank measurement |
| 4. | Needle height setting | Adjust sampling depth for the next sample (how deep the needle should go into the sampling tube) |



(Patient information screen)

The following fields are displayed

Date	Actual timestamp of sample (always synchronized with system time)
Sample ID	Numeric field to enter specific ID. Instrument assigns it automatically. If it is changed, it will be used as a basis for samples, and it will be automatically incremented for each consecutive sample.
Patient ID;	Alphanumeric field to store additional ID
Patient type	Human(default setting) (male,female,baby,toddler, child,control are available)
Patient name	Alphanumeric field for storing Patient name
Birth date	
Sex	Selectable male/female
Doctor	Alphanumeric field



(Displays reference ranges for selected profile)



Database



(Database local menu)

1. Go to specified record Selects one record by time/date , Sample ID, and/or Patient ID (more criteria narrows search)
2. Selection Allows selecting records by specific parameters. Timestamp or various ID's can be used for filtering and selection Also all records can be selected or deselected
3. Change sort order Records are shown according to a so-called "sorting order". This defines whether the latest (time) record should be displayed as the last record, or Patient ID or Sample ID should be used for defining the order. "Unsorted" lists records in their "unsorted" sequence. It is used for servicing functions
4. Manage selected record Selected records can be **Saved, Deleted** or **Transmitted** to a connected computer.
5. Backup to USB drive Records selected by date, or other aspects can be saved to a USB memory device



(Edit sample info)

Opens dialog for editing patient information (patient ID, patient name, birthdate, sex, doctor).



Utilities

1. Maintenance
 1. Cleaning
 2. Priming
 3. Drain chamber
 4. Reagent status
 5. Software upgrade?
2. Calibration
 1. Allows selecting records by specific parameters. Timestamp or various ID's can be used for filtering and selection Also all records can be selected or deselected
 - 2.
3. Change sort order
 1. Records are shown according to a so-called "sorting order". This defines whether the latest (time) record should be displayed as the last record, or Patient ID or Sample ID should be used for defining the order. "Unsorted" lists records in their "unsorted" sequence. It is used for servicing functions
4. Diagnostics
 1. Selected records can be **Saved, Deleted** or **Transmitted** to a connected computer.
5. Settings
6. Service



Prints selected test results



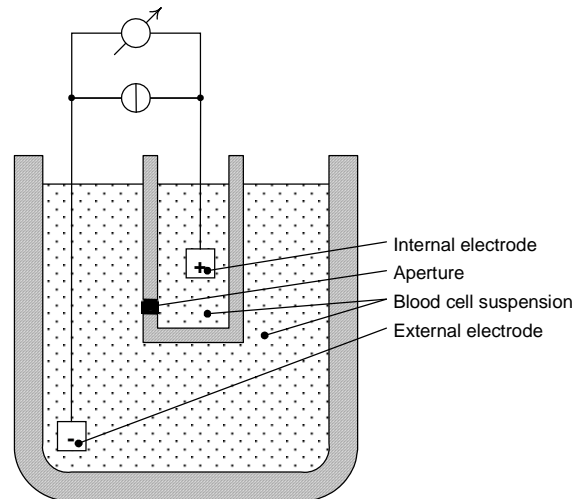
Exit

- | | | |
|----|----------------------------------|--|
| 1. | Shutdown | Shuts off (use if the unit, will not be used for over 72 hours) |
| 2. | Preparing for shipment | Drains and shuts off (use if the unit will be unused for more than 2 weeks, or if it will be shipped) |
| 3. | Logout (only in multi-user mode) | Logs out current user. Pneumatic system remains active. Do not use this item to turn the analyzer off. |

4 OPERATING PRINCIPLES

4.1 Impedance Method

The impedance method (a.k.a. Coulter method) counts and sizes cells by detecting and measuring changes in electrical impedance when a particle in a conductive liquid passes through a small aperture.



4-1 Impedance method

Each cell passing through the aperture – there is a constant DC current flowing between the external and internal electrodes – causes some change in the impedance of the conductive blood cell suspension.

These changes are recorded as increases in the voltage between the electrodes.

The number of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume of that particle. The volume distribution of the cells are displayed on diagrams: WBC (EOS), RBC, and PLT histograms.

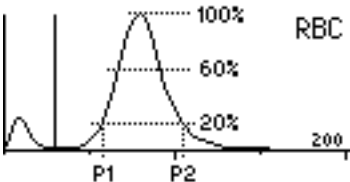
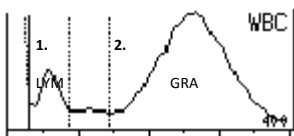
4.2 Principle of HGB Measurement

The lysed sample dilution can be measured by a photometric method. The reagent lyses the red blood cells, which release hemoglobin. The chemical process forms a stable form of methemoglobin.

All Analyticon branded reagents are cyanide free, and thus are environment-friendly. However, some reagents from other manufacturers may contain cyanide. In that case, cyanide and any other chemical composition formed using cyanide is environmentally dangerous. Contact the reagent manufacturer for safety measures. The manufacturer (Analyticon) is not liable for any damage caused by using cyanide based reagents with any of its analyzers.

4.3 Parameters

Hemolyzer 3 measures and calculates 20 parameters, listed below. For each parameter we list the name, abbreviation and measurement unit in the first column. Short description for each parameter is in the second column.

White Blood Cells – WBC (cells/l, cells/ μ l)	Number of leukocytes $WBC = WBC_{cal} \times (cells/l, cells/\mu l)$
Red Blood Cells – RBC (cells/l, cells/ μ l)	Number of erythrocytes $RBC = RBC_{cal} \times (cells/l, cells/\mu l)$
Hemoglobin concentration - HGB (g/dl, g/l, mmol/l)	Measured photometrically at 540 nm; in each cycle blank measurement is performed on diluent $HGB = HGB_{cal} \times (HGB_{measured} - HGB_{blank})$
Mean Corpuscular Volume - MCV (fl)	Average volume of individual erythrocytes derived from the RBC histogram.
Hematocrit – HCT (percentage, absolute)	Calculated from the RBC and MCV values. $HCT_{percentage} = RBC \times MCV \times 100$ $HCT_{absolute} = RBC \times MCV$
Mean Corpuscular Hemoglobin – MCH (pg, fmol)	Average hemoglobin content of erythrocytes, calculated from RBC and HGB values. $MCH = HGB / RBC$
Mean Corpuscular Hemoglobin Concentration – MCHC (g/dl, g/l, mmol/l)	Calculated from the HGB and HCT values. $MCHC = HGB / HCT_{absolute}$ Unit of measurement is displayed according to the one chosen for HGB result (g/dl, g/l or mmol/l)
Red Cell Distribution Width – RDW-SD (fl) Platelet Distribution Width – PDW-SD (fl) Red cell Distribution Width – RDW-CV (absolute) Platelet Distribution Width – PDW-CV (absolute)	The distribution width of the erythrocyte or platelet population derived from the histogram at 20% of peak  $xRDW-SD = RDW_{cal} \times (P2 - P1) (fl)$, $xRDW-CV = RDW_{cal} \times 0.56 \times (P2 - P1) / (P2 + P1)$ by the factor of 0.56 CV is corrected to the 60% cut
Platelet – PLT (cells/l, cells/ μ l)	Number of thrombocytes (platelets) $PLT = PLT_{cal} \times (cells/l, cells/\mu l)$
Mean Platelet Volume – MPV (fl)	Average volume of individual platelets derived from the PLT histogram
Thrombocrit – PCT (percentage, absolute)	Calculated from the PLT and MPV values $PCT_{percentage} = PLT \times MPV \times 100$ $PCT_{absolute} = PLT \times MPV$
White blood cell differential: <ul style="list-style-type: none"> • LYM, LY% : lymphocytes • MON, MON% : monocytes and some eosinophils • GRA, GRA%: neutrophil, eosinophil and basophil granulocytes 	Absolute values counted in the channels determined by the three WBC discriminators:  Percentages calculated from the absolute WBC value.

4.4 Absolute and Linearity Ranges of Measured Parameters

The instrument is guaranteed to provide specified accuracy within its linearity range.

Beyond this linearity range, the instrument is able to display results, but may not guarantee accuracy characteristics.

If the value is over the maximum range of guaranteed linearity, the instrument cannot measure it and the result will be marked with an E (Error) flag.

To measure a sample, whose parameters exceed the maximum value indicated in the table below, pre-dilution is recommended. See section 5.3.1.3 of this manual.

The linearity ranges of primary parameters in normal measuring mode:

Parameter	Linearity Ranges	Maximum	Unit
WBC	0...75	150	10 ⁹ cells/liter
RBC	0...15	20	10 ¹² cells/liter
PLT	0...700	1000	10 ⁹ cells/liter
HGB	0...250	400	g/l
HCT	0...100	-	%
MCV	30...150	-	fI
MPV	3...30	-	fI

4-2 Linearity ranges of parameters

The linearity ranges for 1:5 pre-dilution mode:

Parameter	Linearity Ranges	Maximum	Unit
WBC	2...200	300	10 ⁹ cells/liter
RBC	1...30	40	10 ¹² cells/liter
PLT	100...2000	3000	10 ⁹ cells/liter

4-3 Linearity ranges of Pre-dilution mode

5 ROUTINE UTILIZATION and MEASUREMENT



5.1 Sample handling

Since some time will usually elapse between collection of samples and counting, it is necessary to preserve the sample with an anti-coagulant to prevent large groups of cells forming into clots or lumps of cell matter that will clog the cell counter. Choice of anti-coagulant is very important, as some anticoagulants will affect the shape and size of blood cells. In general, **K3-EDTA** (liquid), preferably potassium based, is the only anti-coagulant recommended for use with electronic blood counters.

Care must be taken when using homemade containers pre-dosed with EDTA. If the container is not filled with enough blood, the ratio of EDTA to blood may reach a level, which results in osmotic transfer from the RBCs, which shrinks them. **The ratio of EDTA to blood should not exceed 3 mg/ml.** Generally, we suggest using pre-manufactured sample tubes containing the necessary amount of EDTA. Also, when taking blood, please make sure that requirements attached to sample tubes are met.

Important! Make sure to fill sample tubes to at least 7-8 mm height with blood otherwise correct sampling cannot be guaranteed! Observe marking on sample tube.

There is another possibility that can help the user to help the analyzer get a reliable sample from the tube: using the needle setting function. This is available in Measurement Local menu, and controls sampling height of the needle inside the sample tube. If you have a sample tube with a higher/lower bottom, you can control the sampling height adjusting this option. This can also help if sample level is too low within a sampling tube.

Needle offset is displayed in the lower left corner of the measurement screen.

Attention! If you hurt yourself during analysis, biohazard substances can cause infection! Always take special care to sharp objects and always use rubber gloves!

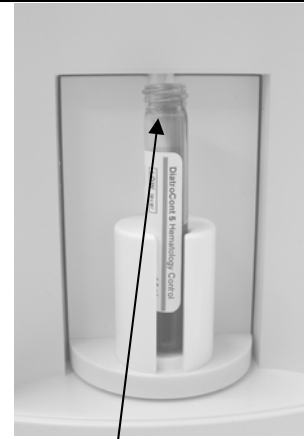
To initiate analysis:

1. *Invert the closed sample tube 8 times to achieve a homogenous sample. Do not shake the sample, because micro-bubbles can form inside which may cause erroneous sampling!*

You have the possibility to use 3 different interchangeable adapters for different tube types. Tube types are shown in the next figures.



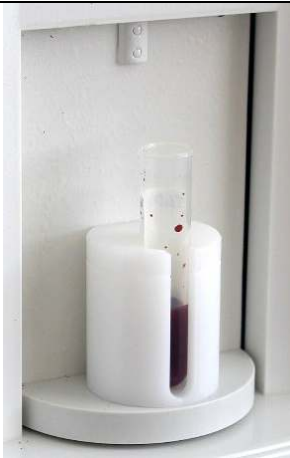
5-1 Vacutainer with sample blood (cap removed)



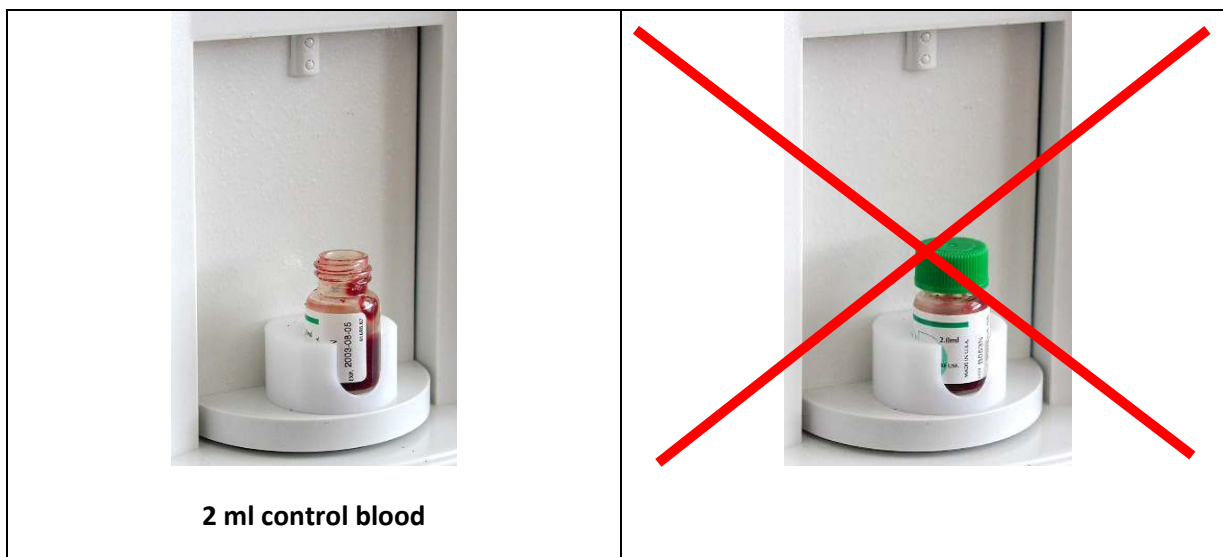
5-2 Sample tube with 5 ml control blood

Please wipe the mouth of the tube because the bursting bubble can dirty the instrument with blood which can cause measurement error at next sample

Below you can see 3 types of tubes (microtainers) used in micro adapters. These are only examples given by us, you can try to use other type of microtainers as well.



Be careful to place the tube with the cap always in the position shown above, otherwise the cap can get stuck when the sample holder turns.



1. Remove the cap!! It is very important because the tip will not pierce the cap!

2. Position the sample tube in the sample rotor.
3. Push START key.


The sample rotor will turn into the inside of the instrument and the needle draws sample from the tube. The aspirating needle is retracted, while its outer surface is automatically rinsed with diluent. This insures the low carry-over between samples. After a few seconds, the rotor turns out. Now you can remove the sample tube from the adapter of the sample rotor.

5.2 Sample analysis

5.2.1 Sample preparation

Use K-EDTA anti-coagulated fresh whole blood as sample. **Prior** to sampling, mix the sample gently by **inverting it 8 times**. **Do not shake the sample**, as this could damage the blood cells.

5.2.2 Modifying lyse quantity

The default lyse quantity can be adjusted by pressing  on the MEASURE screen. Another option is to modify the lyse quantity by ± 0.1 ml or ± 0.2 ml is available during analysis.

Press \uparrow to **increase** the lyse quantity (**+0.1/0.2 ml**) if the separation between lysed RBCs and WBC populations is poorly differentiated, resulting in increased WBC and LYM counts.

Press \downarrow to **decrease** the lyse amount (**-0.1/0.2 ml**) if the WBC histogram seems to be shrunk to the left, i.e. the different WBC populations are overlapped. This can inhibit proper separation of WBC populations.

Param	Low	High	Unit
WBC	5.00	10.00	$10^9/l$
RBC	5.00	5.50	$10^{12}/l$
HGB	120.00	174.00	g/l
HCT	36.00	52.00	%
MCV	76.00	96.00	fl
MCH	27.00	32.00	pg

The two important parameters influencing lysing are lysing time and lyse quantity.

You cannot change the lysing time, as it is adjusted to the lysing reagent supplied by Analyticon.

5.2.3 Sample information

The software allows the user to enter information for each sample that has been, or will be measured. If an external PC keyboard (PS2) is used, it must be connected to the instrument **before** turning the instrument on.

Two options exist for sample information entry:

- immediately before analysis
- in the Database menu

To enter sample information prior to sample analysis, press the Measurement/ Analysis key, and press button on the screen. The following screen appears:

Use the keypad OK key and the and keys to move through the settings.

Use the and keys to change the settings, and the keypad or external keyboard to enter text or numbers.

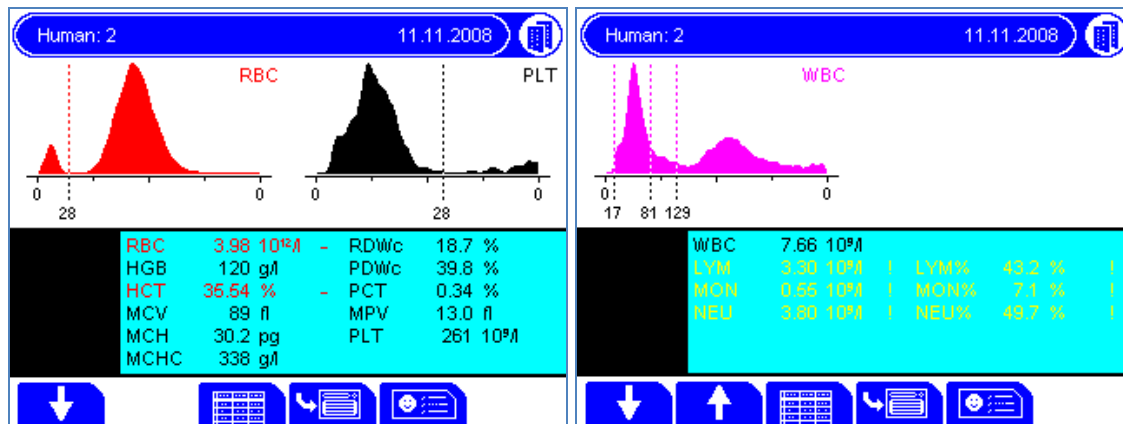
Press the to accept data, cancel with button.

Begin analysis by pressing the Start button.

WARNING! Do not reach inside the instrument, as the needle can cause injury!

5.3 Results

When analysis is complete, the following screen show all measured and calculated parameters as well as the WBC, RBC and PLT histograms. Results, histograms and other terms will be stored automatically in the memory.



Use **↑** and **↓** keys on the screen to move through the results and histograms.

The following table summarizes **warning flags** and explains possible causes and suggests hints to overcome the problem:

Uppercase letters refer to WBC or HGB problems:

Flag	Meaning	Recommended user action
E	No WBC 3-part differential	Possible lyse problem. May occur in pathological lymphocytosis.
H	HGB blank is high, or no HGB blank	Repeat the blank measurement. If HGB blank is not stable there are probably bubbles in the WBC chamber: Run a cleaning and try blank again. Close the side door if open during measurement.
B	WBC blank is high, or no WBC blank	Repeat the blank measurement, or run prime lyse and try blank again. Possible lyse contamination, or noise problem.
C	WBC clogging	Aperture clogging. Perform cleaning and repeat the measurement. If it is a general problem, please contact your Service Personnel. Low temperature reagents can cause it as well (mainly diluent), in this case you will have to wait until they reach room temperature.
M	WBC coincidence is too high. Linearity error.	Please re-run the sample using prediluted mode (see chapter 5.4.1.2)

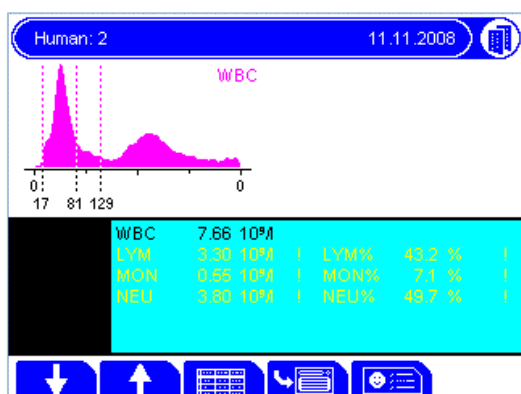
Table 4. Summary of warning flags related to WBC/HGB

Warning flags in lowercase refer to RBC or PLT problems:

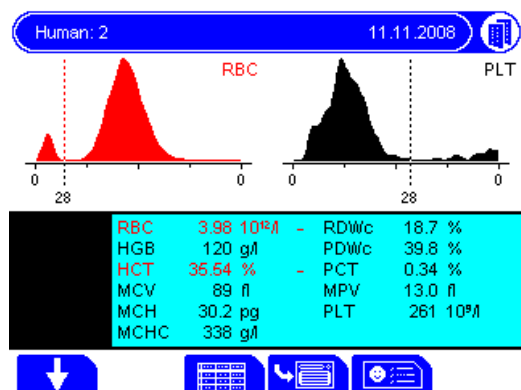
Flag	Meaning	Recommended user action
p	PLT blank is high, or no PLT blank	Run cleaning and repeat the blank measurement. Diluent or system cleanliness problem. If it is stable high, replace the diluent by opening a new tank.
b	RBC blank is high, or no RBC blank	Same action as in case of warning flag p .
c	RBC/PLT clogging	The same action as in case of the C warning flag.
m	RBC/PLT coincidence is too high. Linearity error.	The same action as in case of warning flag M .

Warning flags are grouped according to measurement conditions and according to the problems relating to the blood sample.

Measurement conditions: when the flags are related to clogging (**c**, **C**), probably hemolysing problems (**E**, **b**, **B**, **p**) and pressure problems (Fatal pressure error). In this case, we suggest repeating the measurement.



The exclamation mark flag (!) near a parameter shows some doubt during the evaluation of that parameter. The reason can be a high PLT blank (PLT value will be marked); a case of indefinite discriminator setting (default location is used for some reasons, related parameters will be marked), etc.



Another flagging method is evaluation against the normal ranges. If some of the parameters is out of range it gets a (-) flag if under the range, or gets (+) if over the range. (And the given parameter will be highlighted as well.) You can customize ranges for all kind of patients by setting the corresponding lower and upper ranges. If you set 0 for a range limit, it will be not verified.


5.4 Measurement

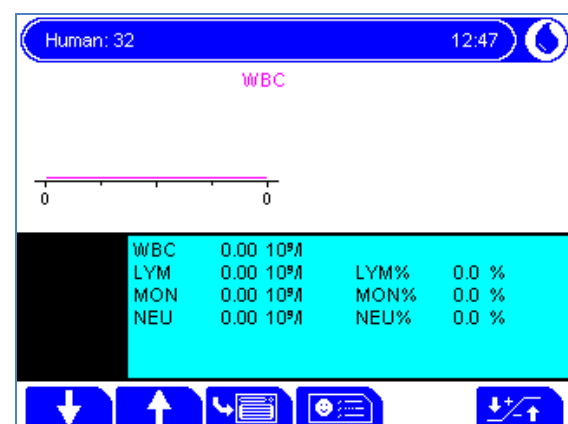
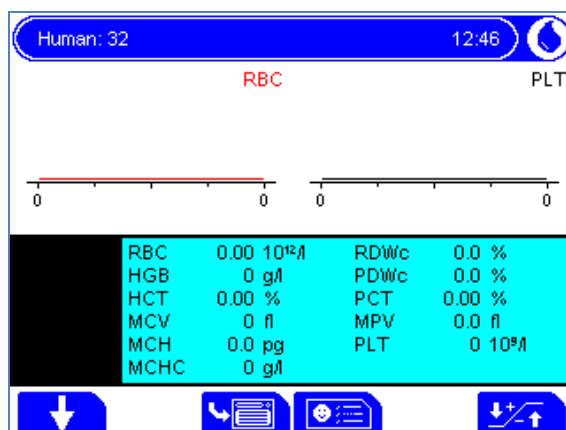
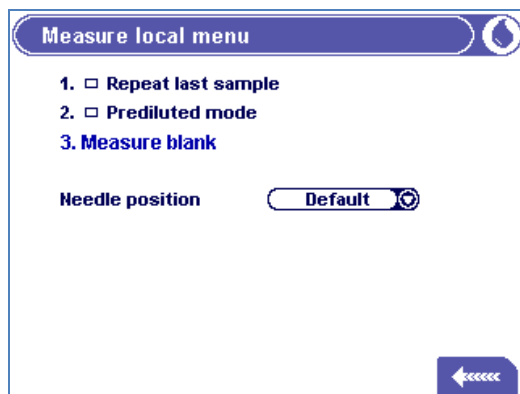
5.4.1 Measure local menu


5.4.1.1 Blank Measurement

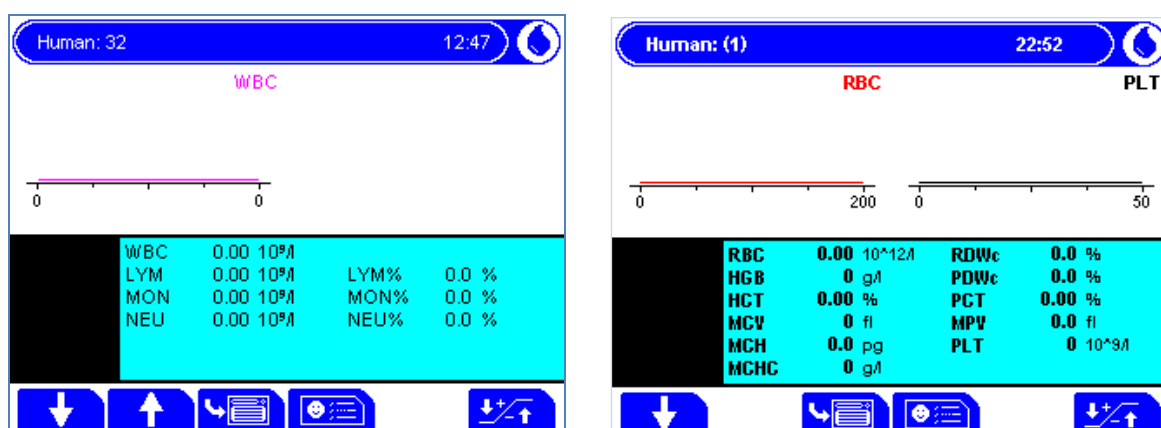
The system uses blank measurements to check cleanliness of the system and reagents. Blank measurement must be performed:

- Once daily, before sample analysis (this is done automatically before the first analysis in MEASURE function).
- After any reagent change (activated manually from the MEASURE/ MEASURE BLANK menu).
- After the replacement of any hardware component that is closely related to the measuring process (aspiration, dilution, counting, rinsing).

Press the Measure key and press the  button on the screen and select Measure blank.



If the Blank measurement was OK, press  to accept the result. The Hemolyzer 3 is then ready for analysis. The instrument then displays a sample measurement screen, as shown, and is now ready to perform an analysis.



There are 3 regions for blank value handling:

1. *Optimal* - all results are within acceptable ranges.
2. *Blank is high* - ! flag is displayed at relevant results.
3. *Blank exceeds acceptability* - no results displayed.

Parameter	1. No flag at parameter	2. ! flag at result	3. E (error) flag at result
HGB	0-10 g/l	10 - 25 g/l	> 25 g/l
WBC	0 - 0.5 x10 ³ cells/μl	0.5 - 1.0 x10 ³ cells/μl	> 1.0 x10 ³ cells/μl
PLT	0 - 25 x10 ³ cells/μl	25 - 50 x10 ³ cells/μl	> 50 x10 ³ cells/μl
RBC	0 - 0.05 x10 ⁶ cells/μl	0.05 - 0.5 x10 ⁶ cells/μl	> 0.5 x10 ⁶ cells/μl

Table 6. Blank measurement ranges

Accepted blank values are essential for proper calibration and quality control measurement. For this reason, no calibration or QC measurement can be performed without accepted blank values.

Quality control measurement and calibration can be performed **only** if all blank values are in the first region (receiving no flags or errors).

If analysis errors occur or the blank measurement is too high, an E error flag appears along with the affected parameter and “---” is displayed instead of results. In this situation, perform a cleaning.

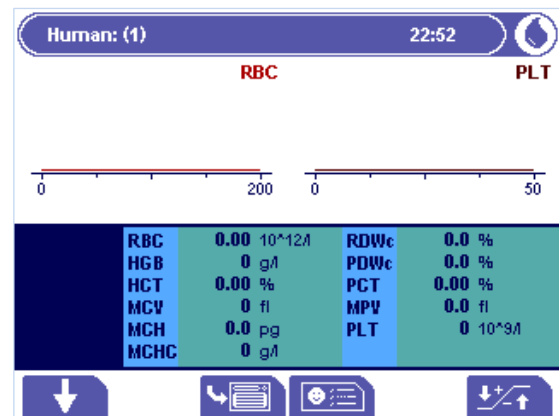
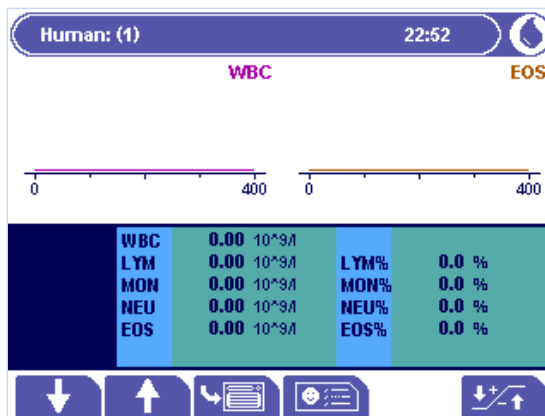
5.4.1.2 Using Pre-diluted Mode

Perform an external pre-dilution of the sample using Hemolyzer 3 reagent diluent, or an isotonic saline solution. Dilute the sample to 1:5 ratio (1 part sample to 5 part diluent). Mix it well.

To perform the analysis:

1. Press the Measurement/Analysis key





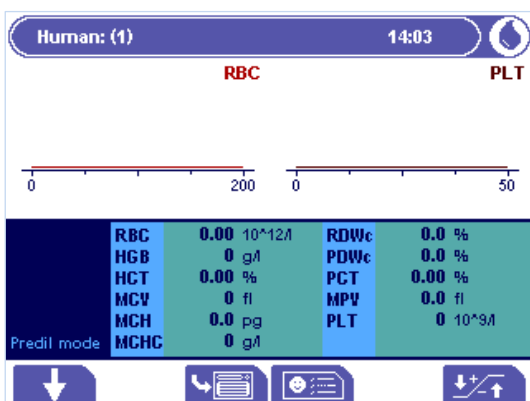
then press the  soft key.

Measure local menu

- ☐ Repeat last sample
- ☒ **Prediluted mode**
- Measure blank

Needle position: **Default**

Select **Prediluted Mode**



Predil mode appears on the left side of the measure screen now.

Edit sample info

Date: 31.03.2008

Sample ID: 1

Patient ID:



Patient type: Human

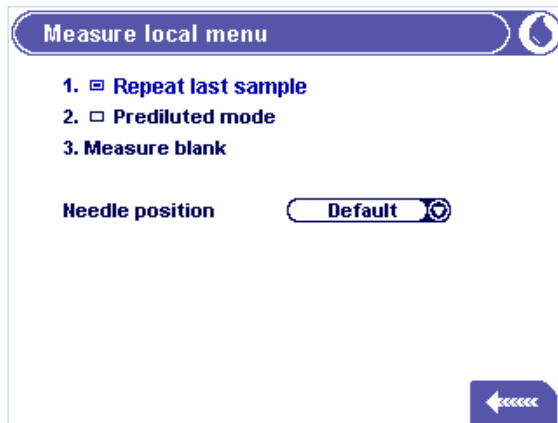
Patient name:

Birthdate: 00.00.0

Sex: ---

Doctor:

If you are processing a new sample. Press the  soft key and enter the patient information, then press .





If you are processing a sample that has already been tested as non-prediluted: select **Repeat Last Sample** to avoid having to re-enter patient information.

Press Start button to begin the analysis. Hemolyzer 3 will automatically calculate the results with the 1:5 pre-dilution factor.




6 DATABASE

Patient results are stored in the memory in chronological order, and can be retrieved at any time. Memorizing capacity is 1,000 measurements, including the complete parameter list, histograms, flags, sample data, and date/time of measurements. If memory is full, latest (actual) record will overwrite oldest record.

To access the Database table, press the Database key  on the front panel. The first screen that appears shows the most recent saved tests.


Database 

Sample ID	Patient ID	Date	WBC
111		01.03.2008 15:43	17.7
112		01.03.2008 15:49	18.0
113		01.03.2008 15:53	17.7
0		01.03.2008 16:11	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:12	0.00
0		01.03.2008 16:13	0.00
0		01.03.2008 16:13	0.00
0		01.03.2008 16:13	0.00
0	Blank	25.03.2008 11:18	0.00
0	Blank	25.03.2008 11:55	0.00




DATABASE

Pressing the ← or → key accesses the remaining, non-visible parameter results. The ↑ or ↓ key scrolls between the results individually.

To display the histograms, press the  soft key.

To print an individual result, highlight the result and press Print .

Database local menu 


1. Go to specified record

2. Selection

3. Change sort order

4. Manage selected records



5. Back up to USB drive



DATABASE LOCAL MENU

From the database table screen, enter the Database local menu by pressing the **Menu** key.

The menu contains the following items:

Command	Function
Go to specified record	Jumps to a particular sample record. Enter the date and time, sample ID, and patient ID of the sample you want to view, and press  . The first sample meeting your parameters is then displayed. If you leave any ID blank (0), records are searched by date/time only
Selection	Selects all sample records in memory, or all having a specific date, time and ID. Select by date, time and ID allows you to select a range of specific records, and Deselects all deselects all records. Entering 0 as an ID searches by date/time only. Corresponding results are marked with a filled box.
Change sort order	Changes the order in which results are displayed: by time, sample ID or patient ID.
Manage selected records	Sends selected records to a PC, deletes them, or saves them to a diskette or USB device. Before selecting Backup selected records, insert a 3.5 inch diskette or connect a USB storage device. An empty floppy diskette can store data for 800 samples.
Backup to USB drive	Backs up all records from a specified day to USB storage device. Select a day to backup, then press  to confirm.

7 UTILITIES

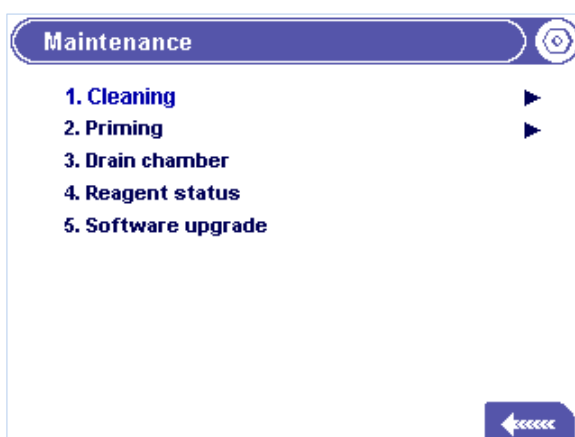
7.1 Maintenance



By selecting item (1) of the UTILITIES you can access the MAINTENANCE menu.

7.1.1 Regular Maintenance Jobs

From Maintenance submenu, the user can initiate maintenance procedures such as cleaning, priming, draining chamber, reagent status.

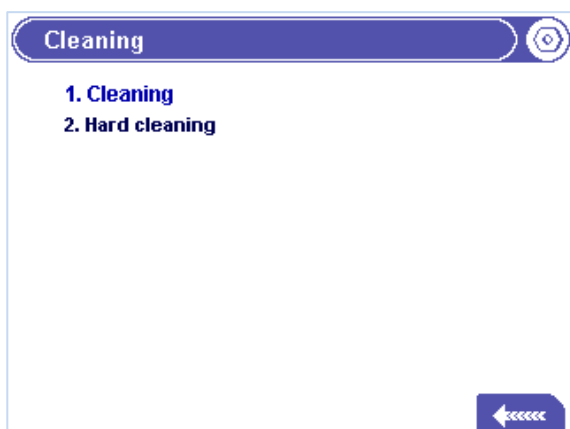


MAINTENANCE

Select the required submenu.

7.1.2 Cleaning

Item 1 in the above menu brings up cleaning functions.



Item 1 starts a washing cycle using the system cleaner reagent. This action is recommended if clogging problems are experienced (C or Q error flag).

Item 2 initiates a process that uses a light solution of hypochlorite (NaOCL), and washes the entire system with it. The instrument will ask for the cleaning solution in a sampling tube.

7.2 Priming

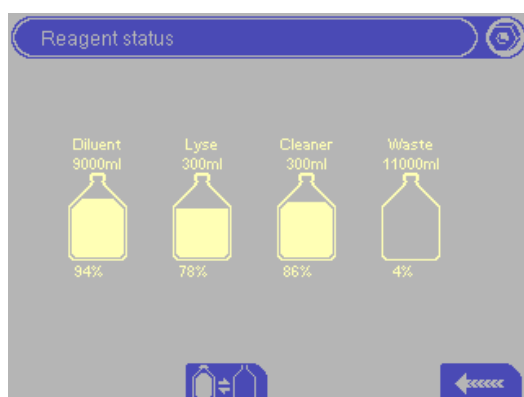


During the priming cycle, the fluidic system is rinsed with a large amount of diluent. It differs from the process in a start-up procedure; as in the latter case a simple filling of the fluidics is performed. If fluid sensors are on, the analyzer makes these procedures automatically, otherwise the User must initiate them activating the appropriate item within this submenu.



7.3 Draining chamber

Draining of the chamber should be run before removal or replacement of parts related to the measuring chambers or apertures (Service personnel task).

7.4 Reagent status

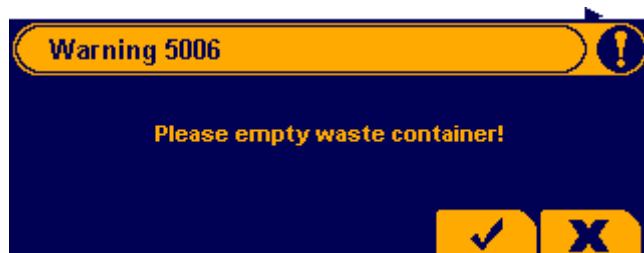


The screen shows reagent volumes in containers, as calculated by the instrument. As measurements are performed, the volumes are changing accordingly. When reagent volume in a container is running low, instrument will notify user, and ask replacement.

Press the  soft key, then press  to confirm.

Hemolyzer 3 updates the installation date, reagent lifetime, and the amount of reagent in each container.

7.4.1 Empty waste container



The software counts the waste container capacity and gives warning message when the tank is full.

Empty the waste tank when this warning message appears.

Service Personnel can modify the waste container capacity on Service level.

8 MAINTENANCE

8.1 User-accessible parts

On the left side of instrument there is a side door, which allows reaching the fluidic system and the mechanical parts easily (Figure 11).

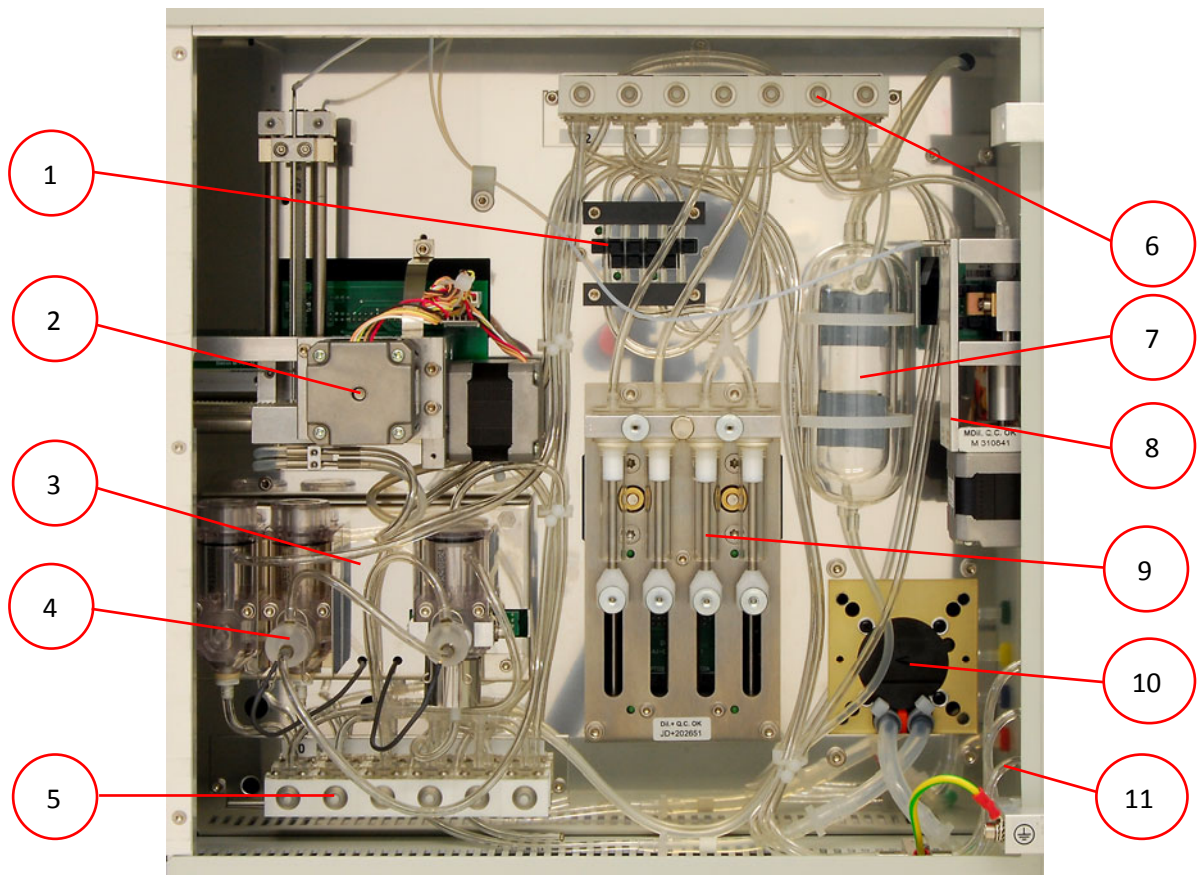


Figure 7. Fluidic and mechanical parts

1. Reagent sensor
2. Needle moving mechanics
3. Amplifier assembly
4. Chambers and apertures
5. Valve block 1-5
6. Valve block 6-12
7. Puffer reservoir
8. Micro dilutor
9. Dilutor
10. Peristaltic pump
11. Reagent inlets

8.2 Maintenance schedule

WARNING! **User is allowed to repair only parts that can be found behind the side door!**
 User must not remove any covers of analyzer!
 User must not disassemble the power supply unit!

8.2.1 Daily, before daily routine:

Check reagent condition: go to reagent status screen, check if the liquid amount in reagent containers is enough for the expected number of daily measurements.

Check the content of waste tank, if the level is above 80% it is recommended to dispose as described in chapter 7.4.1.

Check the existence of air bubbles at rear reagent liquid connectors and syringes (except waste line). In case of bubbles run prime reagent function at regarding reagent

Check instrument performance: run blank measurement, if the result is acceptable, accept and save result with ☒, otherwise run cleaning, and repeat blank measurement.

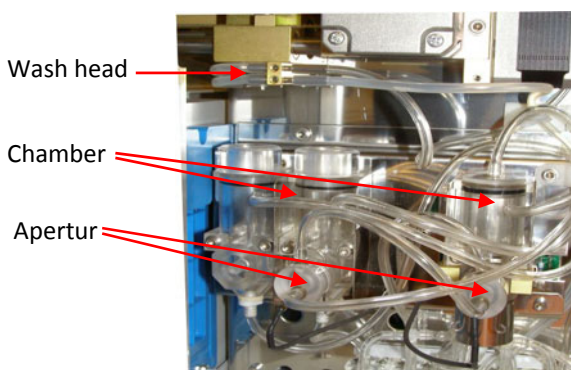
Run QC samples according to the regulations of laboratory. If there are no other rules, run at least normal control, and check if the results are in range. Use the QC menu of instrument!

8.2.2 Daily, after daily routine: Run Cleaning process in Maintenance menu.

8.2.3 Weekly:

Hard cleaning: pour 1ml of 2% Sodium Hypochlorite solution into a sampling tube, run hard cleaning procedure. It removes remainders of blood samples measured during the daily routine.

Clean washing head: The washing head cleans the outer surface of the aspirating tip with saline diluent. Any salt build-up on the lower surface may cause malfunction during operation. Use warm tap water and a soft cloth to clean this area. You can see the washing head indicated in the following figure:



Exit the Measurement menu. Open the side door after the needle has stopped moving.

Gently rub the lower surface of the washing head to remove the salt build-up.

Close the side door.

8.2.4 Semi-annual:

Run self test: as it is written in chapter 7.4.2. If the overall result is “Errors”, print out the result and call service.

Pump maintenance: The pump installed in the instrument is maintenance free. The guaranteed lifetime of tube is one year. However, would you experience:

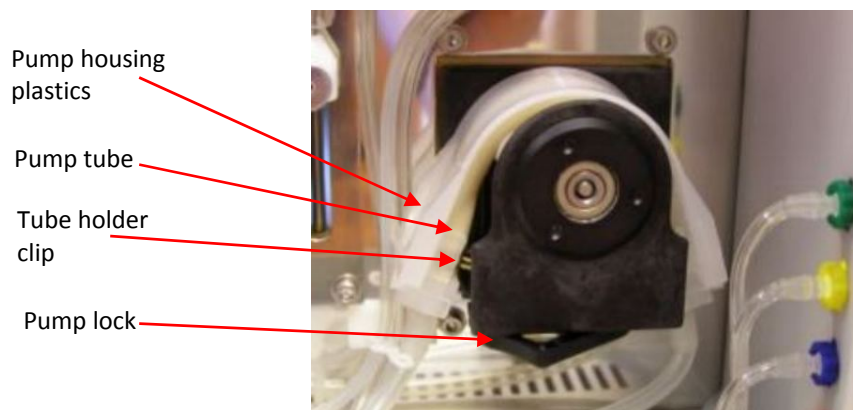
- leakage from the pump,
- vacuum error displayed during measurement,
- vacuum or drift values are out of range in self test, you may replace the tube.

Tube replacement procedure:

Open the side door.

Open the pump lock by turning the plastic holders to release the pump housing plastics (see figure below)

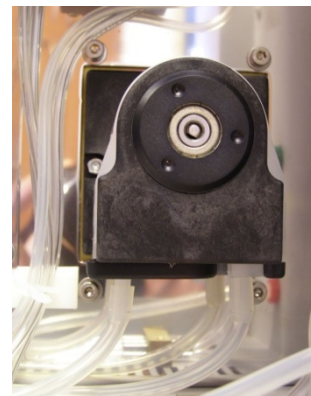
Snap out the pump tube (yellow in color) from the housing.



Replace the tube into the housing plastics, then guide in both ends into the lock.

Turn back the lock to secure the tube in place. Check the connections for proper placement. Close and lock the side door in.

After tube replacement, the pump should look like the figure on the right.



8.3 Calibration

The Hemolyzer 3 is pre-programmed to monitor HemolyzerCont 3 control. Performing QC determinations regularly verifies continued optimal performance.

It is recommended to do calibration in the following cases:

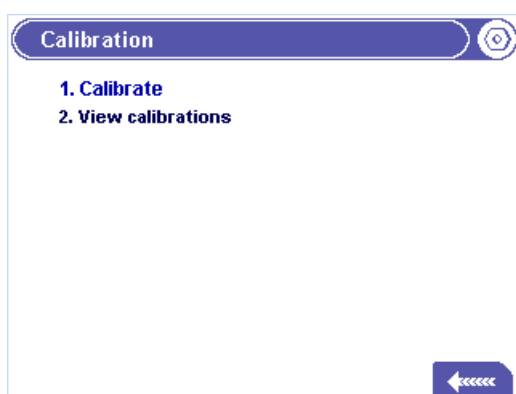
1. At analyzer installation, before beginning the analyses.
2. After replacing any component, related to the process of dilution or measurement.
3. When quality control measurements show any systematic error (bias) or they are outside predefined limits.
4. At regular time intervals (determined by the lab itself).
5. If you want to use the instrument in Prediluted mode.

Calibration can be performed in two ways:

1. User can enter calibration factors - without any calibration measurements – using the numerical keypad.
2. One-, or three-fold measurements of control or special calibration material with known parameters. In this case, the instrument automatically calculates new factors using the following formula:

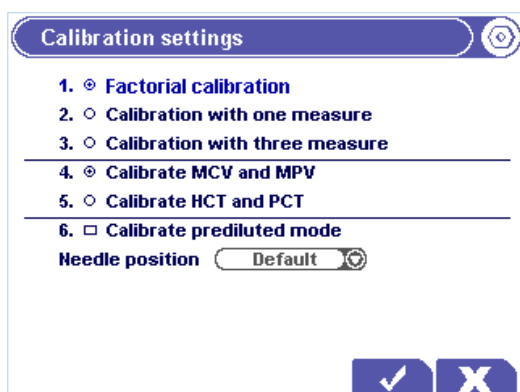
$$\text{New factor} = \frac{\text{Assigned value} \times \text{Stored factor}}{\text{Measured value(s) (or average of those)}}$$

CAUTION! **New calibration will invalidate the previous factors. Old values cannot be retrieved, but can be reviewed in the VIEW CALIBRATIONS menu.**



Start Calibration by choosing Calibration in the UTILITIES menu.

Select Calibrate (1 item).




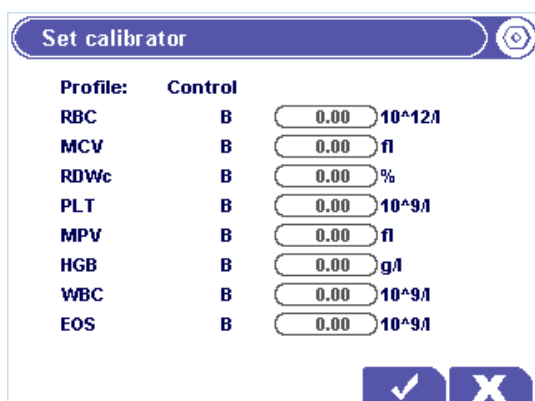
Calibration settings

- 1. ☒ Factorial calibration
- 2. ☐ Calibration with one measure
- 3. ☐ Calibration with three measure
- 4. ☒ Calibrate MCV and MPV
- 5. ☐ Calibrate HCT and PCT
- 6. ☐ Calibrate prediluted mode

Needle position

✓ X

Select calibration mode, press  button and the Set calibrator screen appears.



Set calibrator

Profile:	Control	
RBC	B	<input type="text" value="0.00"/> $10^{12}/l$
MCV	B	<input type="text" value="0.00"/> fl
RDWc	B	<input type="text" value="0.00"/> %
PLT	B	<input type="text" value="0.00"/> $10^9/l$
MPV	B	<input type="text" value="0.00"/> fl
HGB	B	<input type="text" value="0.00"/> g/l
WBC	B	<input type="text" value="0.00"/> $10^9/l$
EOS	B	<input type="text" value="0.00"/> $10^9/l$

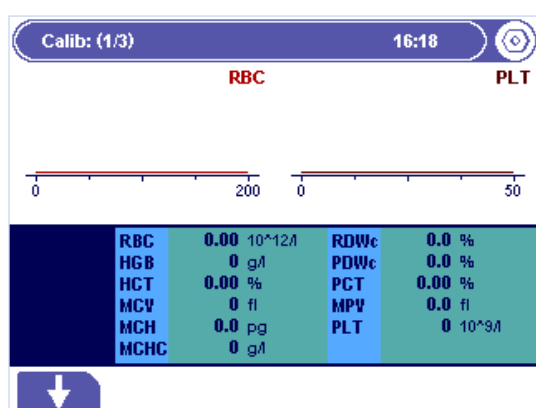
✓ X

If automatic (1 or 3 measurement) calibration is selected, upon starting the calibration you will have to enter assay values for each parameter from the calibrator package insert.

Target values for calibrated parameters can be set within the following ranges:

Parameter	Low limit	High limit
RBC	1.00	8.00
HCT	0.1	0.6
MCV	50	120
RDW CV	10	50
PLT	30	800
PCT	0	2
MPV	5	15
PDW CV	5	50
HGB g/l	30	300
WBC	1.0	30.0

Table 7. Calibration ranges



When all parameters are set, press the soft key. The display shows Calib:(1/3) at top left.

Start analysis of the control material.

When the analysis is finished, the display will show results. If no abnormal values or flags show, , press . You have to accept (Confirm) calibration

measurement results. If you fail to accept (Confirm) the result, the actual sample cannot be used for calibration, and you have to run the sample again.

Upon finishing the last sample, Hemolyzer 3 calculates and displays the new calibration factors.

8.4 Quality Control Procedure

By analyzing control materials, day-to-day reproducibility can be monitored. In this submenu, both target values and acceptable ranges for each parameter can be specified for different QC levels.

NOTE: Target values of the control material should be set only once, at the beginning of the QC measurements. Resetting parameters deletes previous QC results of the active level.

CAUTION! Any change in the QC material setting deletes previous QC results. It is strongly recommended to print results prior to changes.

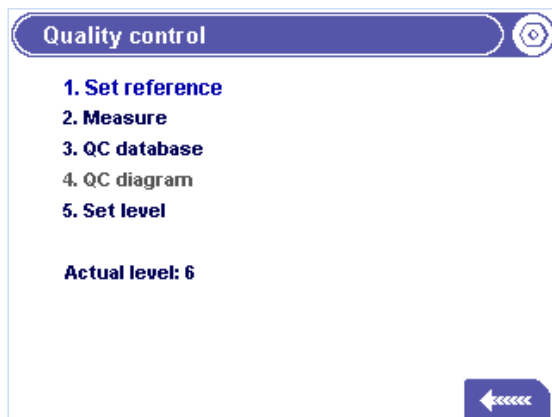




In the Quality Control menu select **Set QC reference ranges**:

Set QC Reference values:


Enter the value ranges for each test parameter as indicated on the paperwork accompanying the QC lot number you are using.

- use the keypad to change displayed values.
- to disable QC of a parameter, set it to 0.0
- use the PGDN and PGUP to view additional parameters.

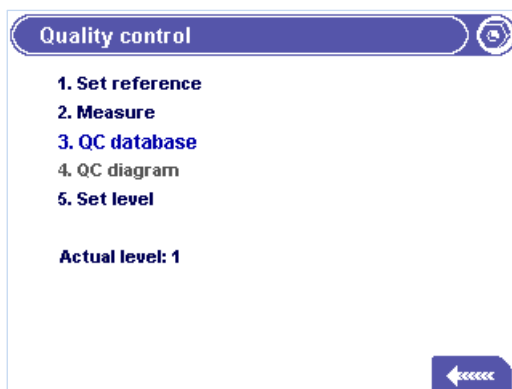


Press  to accept the data, then press  again to confirm.

Measurement mode is activated. Prepare the calibrator sample (Control) and insert it into the sample holder. Press the Start button to start calibration.

Press  to accept the results and save them in the QC database

Viewing the Accepted QC Database

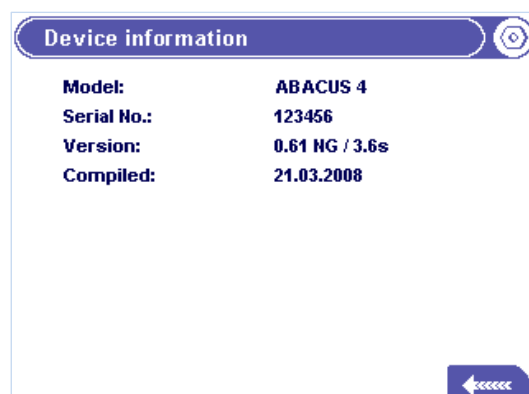
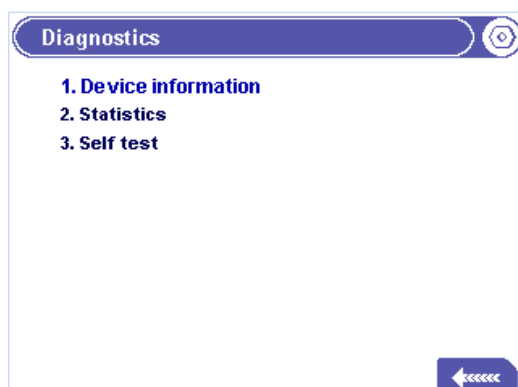


Press the Utilities key, then select Quality Control.

Select **QC database**.

8.5 Diagnostics

8.5.1 Device Information



8.5.2 Self Test

The Self test is a procedure to verify proper operation of essential components of the instrument.

The Self test should be performed:

Self test		
Date of testing	12.03.2009	
Model	ABACUS 3	
Serial No.	123456	
Version	0.1 DEV / 3.6s	
Compiled	17.11.2008	
Overall result	ERROR	
HGB dark	0	OK
HGB light	6288	OK

At installation.

After replacing any component.

After extended time out of use.

Press the **Utilities** key and select **Diagnostics**.

Select **Self test**. Hemolyzer 3 then lists and checks subsystems.

When the test is finished, the Hemolyzer 3 displays a summary of the results.

8.6 Settings

Utilities Menu	
1. Maintenance	▶
2. Calibration	▶
3. Quality control	▶
4. Diagnostics	▶
5. Settings	▶
6. Service	▶

Selecting item five (5.Settings) of the UTILITIES you can access to this menu.

Printers, fluid sensors, date and time can be set and defined.

8.6.1 Printer settings

Printers	
1. Settings	
2. Information	

Selecting item one (1.Printers) from SETTINGS menu brings up the Printers submenu.

Printer: you can choose between built-in printer or a USB connected external printer.

If the name of the USB printer appears in the list, the printer is supported.

Selecting item two (2.Information) from Printers you can print a test page to check correct settings.

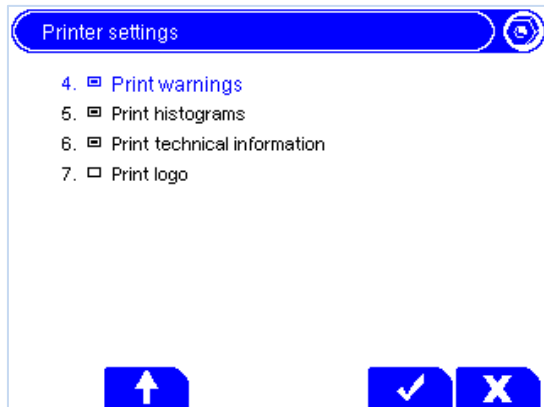
Margin unit: this one can be inch or cm.

Top margin: is used for determining the distance between the upper edge of the sheet and the printed report.

Printer settings	
Printer	Built-in
Margin unit	cm
Top margin	0.5
Left margin	0.5
Quality	Normal
1. <input type="checkbox"/> Enable color print 2. <input type="checkbox"/> Enable auto print 3. <input checked="" type="checkbox"/> Print parameter limits	

Left margin: is used for determining the distance between the left edge of the sheet and the printed report.

1. ☐ Enable color print: The printout can be color or monochrome.
2. ☐ Enable auto print: If enabled, instrument prints results automatically at the end of analysis.
3. ☐ Print parameter limits: Enable or disable parameter limit printing.



4. ☐ Print warnings: Select ☒ to print warning flags that appeared in the result.

5. ☐ Print histograms: Enable / disable graph printing.

6. ☐ Print technical information: Selecting ☒ probe voltages (WBC,RBC), Lyse volume and software/firmware version appear in the printout.

7. ☐ Print logo: Selecting ☒ the Analyticon logo will

be printed on the printout.

Press the  soft key to save the settings.

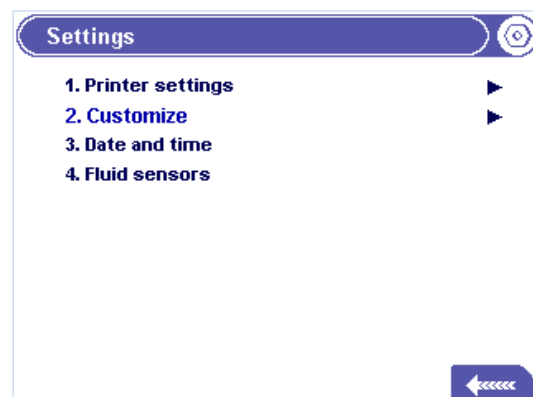
8.6.2 Customize

Use the Customize menu to set the language and date format used by the Hemolyzer 3, along with the screen saver delay, and the date range used for printing combined results from the Hemolyzer 3.

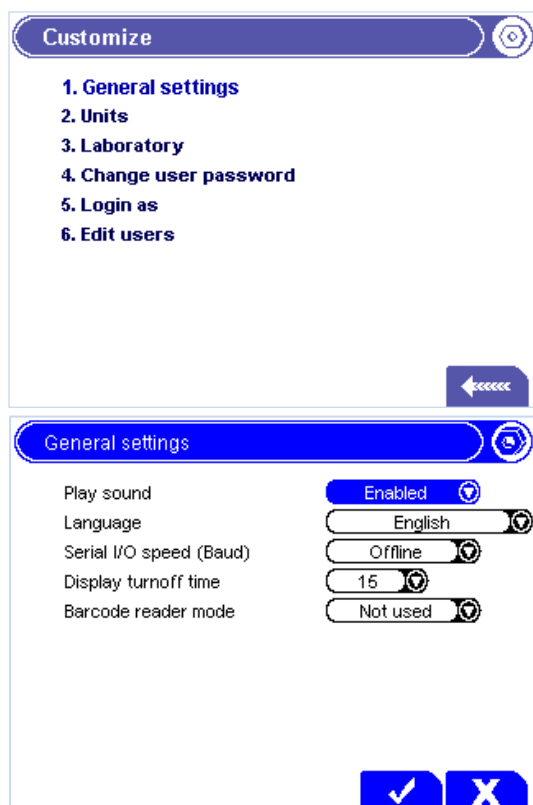


Press the **Utilities** key .

Select **Settings**



Select **Customize**



Select **General Settings**

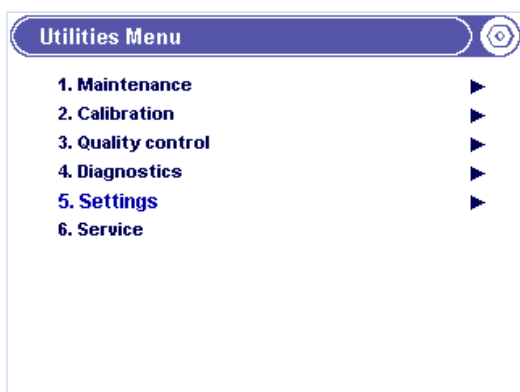
This is a collection of settings influencing instrument operation, customization.

The table below describes available settings.

Play sound	Allows switching the sound signal on/off
Language	All messages and screens will be displayed in the selected language.
Serial I/O speed (Baud)	Offline, USB, Baud rate (9600-115200). Protocol used by Hemolyzer 3 to communicate with a connected computer. -if the instrument is not connected to a computer, choose Offline; -if the instrument is connected computer using USB cable, choose USB.
Display turnoff time	You can set the time after how many minutes the LCD light will turn off when not using the instrument
Barcode reader mode	The barcode reader identifier can be indicated in the Sample ID field or in the Patient ID field

8.6.3 Units

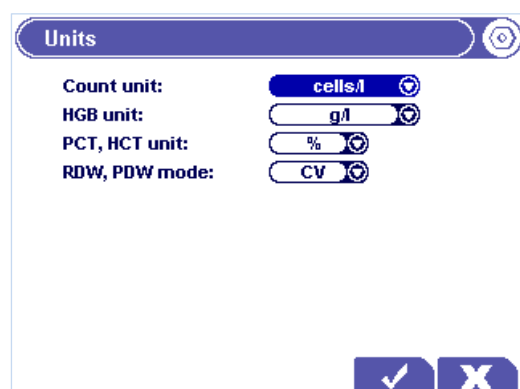
Use the unit menu to set the measurement units the Hemolyzer 3 will use.



Press the Utilities key 

Select **Settings**.

Select **Customize**.




Select **Units**

Set the units as needed:

- Use ↑ and ↓ arrow keys to select a unit
- Use the ← and → arrow keys to select a setting for the units.

The table below lists available unit settings.


Count unit	cells/liter(cells/l), cells/μl(cells/ μl).
HGB unit	grams/liter(g/l), grams/deciliter(g/dl), millimols/liter(mmol/l),
PCT,HCT unit	%, absolute(ABS)
RDW,PDW mode	standard deviation(SD), coefficient of variation(CV)

Press the  on-screen key to save the settings.

8.6.4 Laboratory information

Enter your clinic or laboratory information as follows, to be printed automatically on report headers. You can also use this procedure to edit or change this information.

Enter the name and address of your clinic or laboratory. Press OK to move to the next line.

Press  to accept the settings.

8.6.5 User mode settings

If you want to require users to log in and enter passwords to use Hemolyzer 3, and to be able to track individual usage of the unit, you can enable the Hemolyzer 3's Multi user mode. This will require each user to have a unique user ID and password.

Press the **Utilities** key.

Select **Settings**.

Select **Customize**.

Select **User modes**. - This is where multi-user mode can be activated

After activation, users can be added, disabled (not deleted) and modified


Follow the on-screen instructions to enable multi user mode, to add or modify users, or to change a user's password.


8.6.6 Date and time

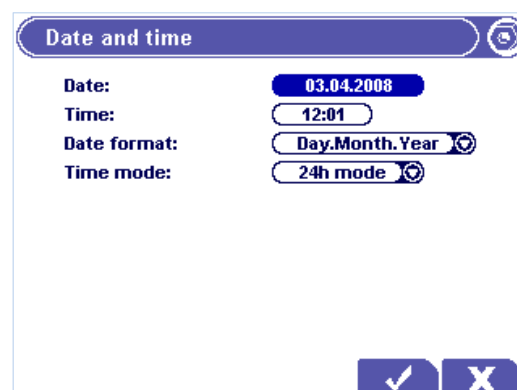
The date and time of each analysis is stored with the results. This menu allows setting the built-in clock and the format of the date displayed.

Press the **Utilities** key, and then select **Settings**.

Select **Date and time**.

Type in the date and time, then press .

Select formats for displaying the date (item 1, 2 or 3) and time (item 4 or 5), then press  to accept the settings



The image shows a 'Date and time' settings screen. It has a title bar 'Date and time' with a circular icon on the right. Below the title bar, there are four rows of settings: 'Date:' with a value of '03.04.2008', 'Time:' with a value of '12:01', 'Date format:' with a dropdown menu showing 'Day.Month.Year' and a checkmark icon, and 'Time mode:' with a dropdown menu showing '24h mode' and a checkmark icon. At the bottom right, there are two buttons: a checkmark icon and an 'X' icon.

Setting	Value
Date:	03.04.2008
Time:	12:01
Date format:	Day.Month.Year
Time mode:	24h mode

9 Printing

This chapter covers information on making reports on measured samples.

9.1 Printouts

When required, the following items can be sent to an external printer or to a built-in printer by

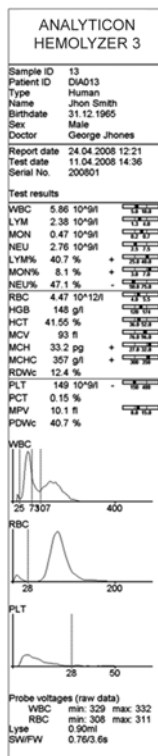
pressing the  function key button.

* Database result(s) (table format)

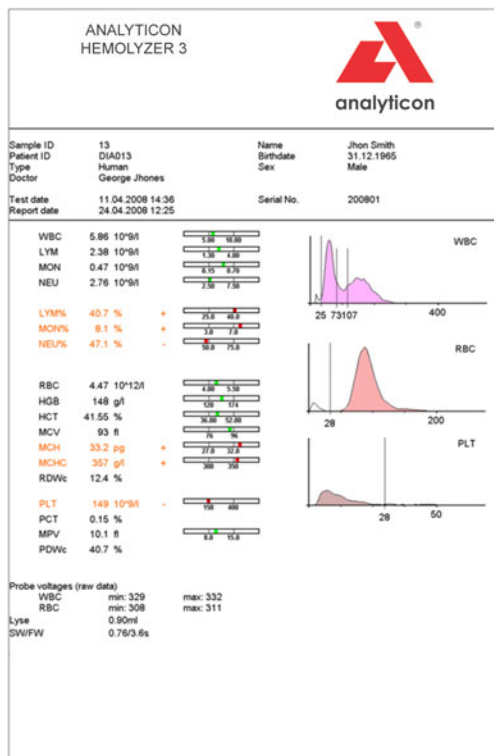
- Database (specified patient results with histograms)
- QC result (Levey-Jennings chart)
- QC result(s) (table format)
- Calibration results
- Last measured blank result
- Last measured patient result (with histograms)
- Last measured QC result
- Device information and statistics
- Self test result
- Set parameters

The appropriate printout format can be selected in UTILITIES/SETTINGS/PRINTER SETTINGS).

Thermal paper printout

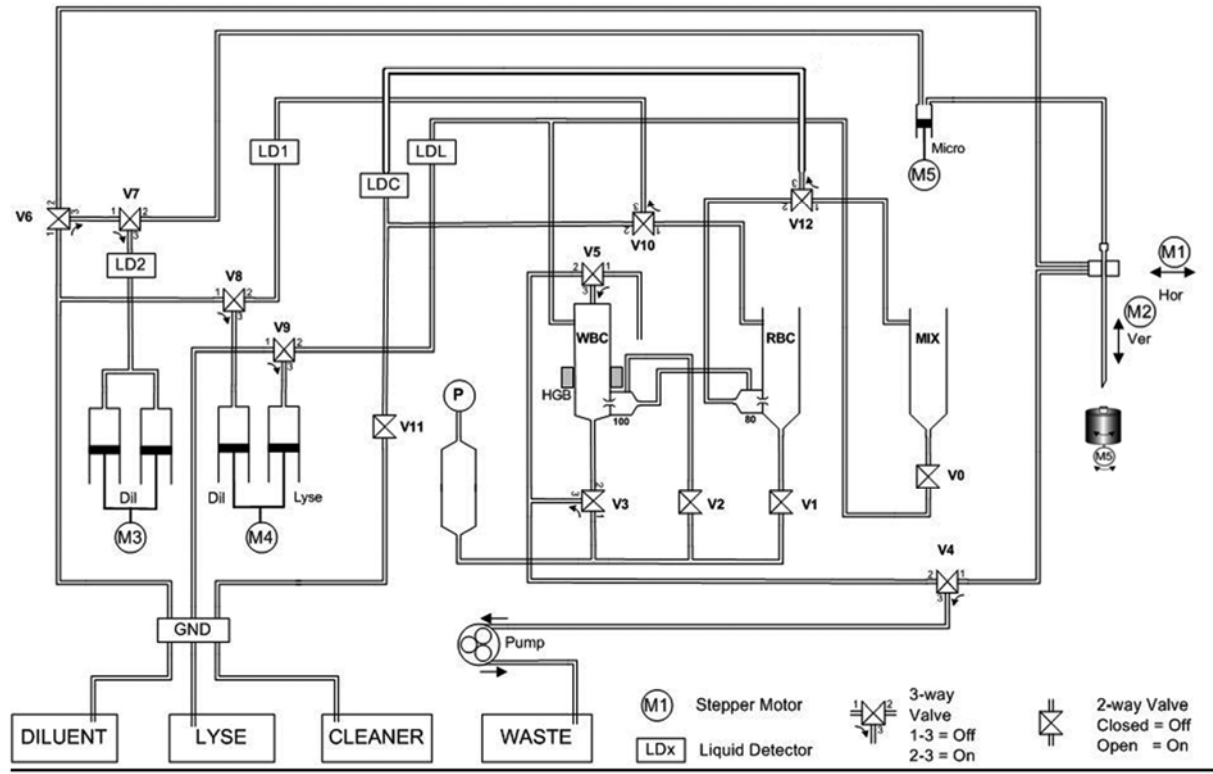


Printout on external printer (color)



10 Fluidic Schematics

Hemolyzer 3 Fluidic Schematics



11 Warning labels on the analyzer





Label	Meaning	Explanation	Chapter
	Biohazard	The sample and the waste are potentially infectious material	2.2.4
	Corrosive	Reagents may cause corrosion or skin irritation.	2.2.4; 2.3
	Warning	General warning of injury.	
	Sharp needle warning	The sampling needle may cause injury.	5.2.3

Table 6. Warning labels